



K 003700

FEB 20 2001

Summary of Safety and Effectiveness Information

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Thomas M. Maguire

DEVICE NAME: Synthes Hamstring Loop

CLASSIFICATION: Class II, 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.

PREDICATE DEVICE: Linvatec BioScrew® Absorbable Interference Screw; Linvatec Interference Screws.

DEVICE DESCRIPTION: The Synthes Hamstring Loop is a two-piece, titanium alloy construct design characterized by: 1) a threaded body, providing for device fixation to the bone tunnel; and 2) a non-threaded, swiveling eyelet that the graft attaches to. An optional extension cap is also available.

INTENDED USE: The Synthes Hamstring Loop is used to:

- Provide femoral and/or tibial fixation in anterior cruciate ligament reconstruction using soft tissue graft (semitendinosus, gracilis).
- Provide fixation during posterior cruciate ligament reconstruction

MATERIAL: Titanium alloy



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 20 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas M. Maguire
Project Leader, Regulatory Affairs
SYNTHES (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K003700

Trade Name: Hamstring Loop
Regulatory Class: II
Product Code: HWC
Dated: November 29, 2000
Received: December 1, 2000

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

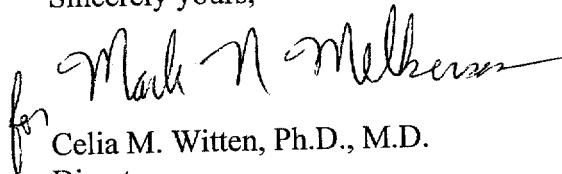
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. Thomas M. Maguire

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Melker

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0 Indications for Use Statement

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510(k) Number (if known):

K003700

Device Name:

Synthes (USA) Hamstring Loop

Indications/Contraindications:

The Synthes Hamstring Loop is used to:

- Provide femoral and/or tibial fixation in anterior cruciate ligament reconstruction using soft tissue graft (semitendinosus, gracilis).
- Provide fixation during posterior cruciate ligament reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. McKenna
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

Prescription Use yes
(Per 21 CFR 801.109)

510(k) Number

K003700

OR

Over-The-Counter Use No